

**Sarns<sup>TM</sup>**  
**TCM II**



# Operators Manual

# Sarns™ TCM II Operators Manual

4415 115 V with Cardioplegia (3M I.D. No.98-0702-0629-1)

4416 220-240 V with Cardioplegia (3M I.D. No.98-0702-0627-5)

## Cautions

**Caution:** FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Proper surgical procedures and techniques are the responsibility of the medical profession.

It is the operator's responsibility to use, check, and maintain this device according to the labels of the product, accompanying instruction manuals, and any revisions of the labeling or instructions that may be subsequently issued.

## Service Policy

Contact Sarns Service, your local 3M subsidiary or your authorized Sarns distributor and describe the problem before attempting to service or return this device. Instructions will then be given for correcting the problem or returning the device and a Returned Goods Authorization (RGA) number will be issued.

Returned devices must be packaged with adequate protection against shipping damage. Include a note describing the problem, stating the RGA number, and giving the name, address, and telephone number of a person to contact for additional information.

In the United States, contact the Sarns Service Department:

**Sarns**  
**3M Health Care**  
6200 Jackson Road  
Ann Arbor, Michigan 48103 U.S.A.  
Telephone: (313) 663-4145 or (800) 262-3304  
Telex: 4930455 SARSVC

Outside the United States, please contact your local 3M subsidiary, your authorized Sarns distributor or the International Department at Sarns.

Telephone: (313) 663-5123  
Telex: 4930456 SARINC  
Facsimile: (313) 663-3944

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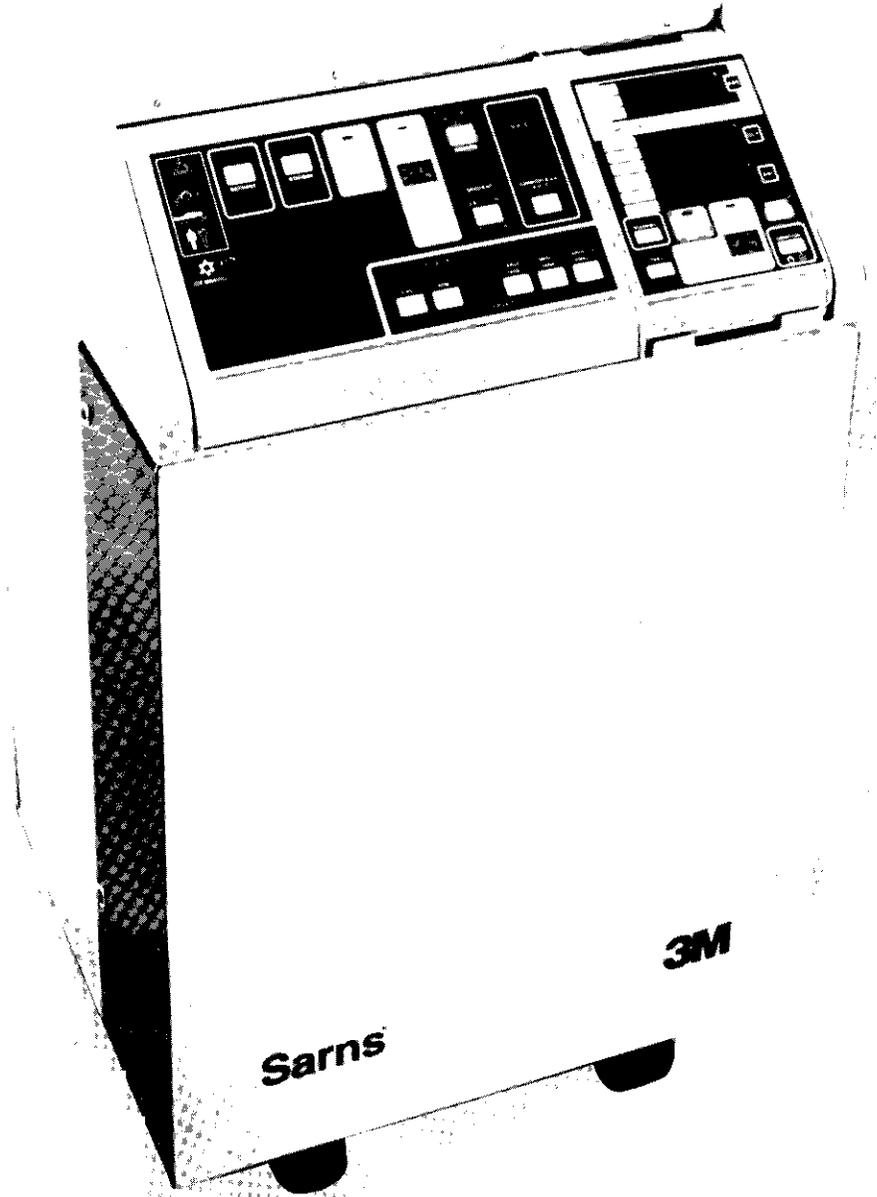
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I F C H E O D D A



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# Product Definition

## Description

The Sarns™ TCM II (system) is a source of temperature-controlled water for blood heat exchangers used in an extracorporeal circuit and for blankets to externally heat or cool the patient. It also freezes water for an ice supply, monitors temperatures in the patient and extracorporeal circuit, and allows gradient re-warming relative to a venous blood temperature.

The Sarns™ TCM II also features a Cardioplegia system which will supply cooling water for cardioplegia.

Note: For a complete description, see the Specifications, Functional Description, and Theory of Operation in the Product Description section of this manual.

## Indications

The Sarns™ TCM II is indicated for controlling and monitoring patient temperature.

## Contraindications

This device is not designed, sold, or intended for use except as indicated.

## Warnings

It is the operator's responsibility to use the Sarns™ TCM II and any attached equipment according to the manufacturer's instructions and good medical practices.

The Sarns™ TCM II is not completely automatic; responsibility for monitoring patient temperatures and rate of temperature change remains with the operator.

To obtain accurate temperature readings, use only probes specified by Sarns for use with the Temperature Probe Module.

Take care when displaying the alarm setting. Depressing the alarm switch for more than 1 second will change the alarm setting.

## Precautions

The system must be properly primed; running the pumps and heaters with the device dry will damage them.

The water level in the large tank must never rise above the maximum level as water may damage the inside of the unit; this water level should not drop below the minimum level as there may be a loss of system performance (see maximum-minimum label).

The Sarns™ TCM II requires a dedicated 20 Amp power source for the 115 volt model and a dedicated 15 Amp power source for the 220-240 volt model.

Grounding reliability can only be achieved when this equipment is connected to an equivalent receptacle marked "Hospital Use" or "Hospital Grade" which has been inspected for proper grounding.

Use care when handling the Temperature Display Module; the controls, displays, or circuitry may be damaged if the module is dropped, struck, or immersed in water.

Use only glutaraldehyde based disinfectants such as Cidex™, Glutarex™, or Sporiciden™\*, as other cleaning agents may cause corrosion.

Do not use chemical solvents such as alcohol, ether, acetone, etc. in or on any part of the system as such solvents may be destructive to the device. Do not spill anesthetics on the system or accessories as chemicals such as Forane (isofluorane) may be destructive.

Remove any lint from the refrigeration coils to prevent damaging the ice maker. Take care when cleaning the refrigeration coils as the coils have sharp edges.

\* Cidex is a trademark of Johnson & Johnson, New Brunswick, NJ, USA; Glutarex is a trademark of 3M, St. Paul, MN, USA; Sporicidin is a trademark of Sporicidin International, Rockville, MD, USA

# Controls and Displays

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## Main Unit

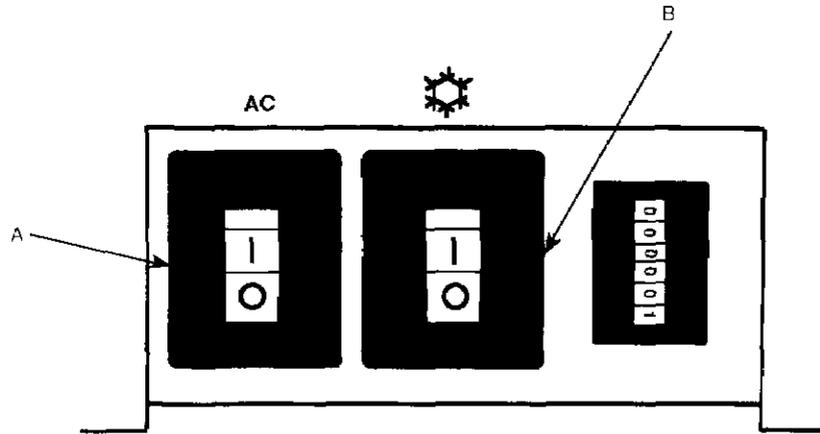


FIGURE 1: SIDE PANEL

- A. System Power Switch turns the system power on and off and serves as a circuit breaker for the system.
- B. Ice Maker Switch turns the ice maker on and off and serves as a circuit breaker for the compressor. When the ice maker switch is on the compressor cycles on and off as needed to make and maintain an ice block.

# Controls and Displays

## Main Unit (Continued)

Modes are started by depressing the mode switch; modes are stopped by selecting another mode. The Defrost mode is unique in that it may be entered only from the Standby mode and is stopped by returning to the Standby mode. All select switches must be depressed for at least 1/2 second to register. A green LED lights to indicate which functions are selected.

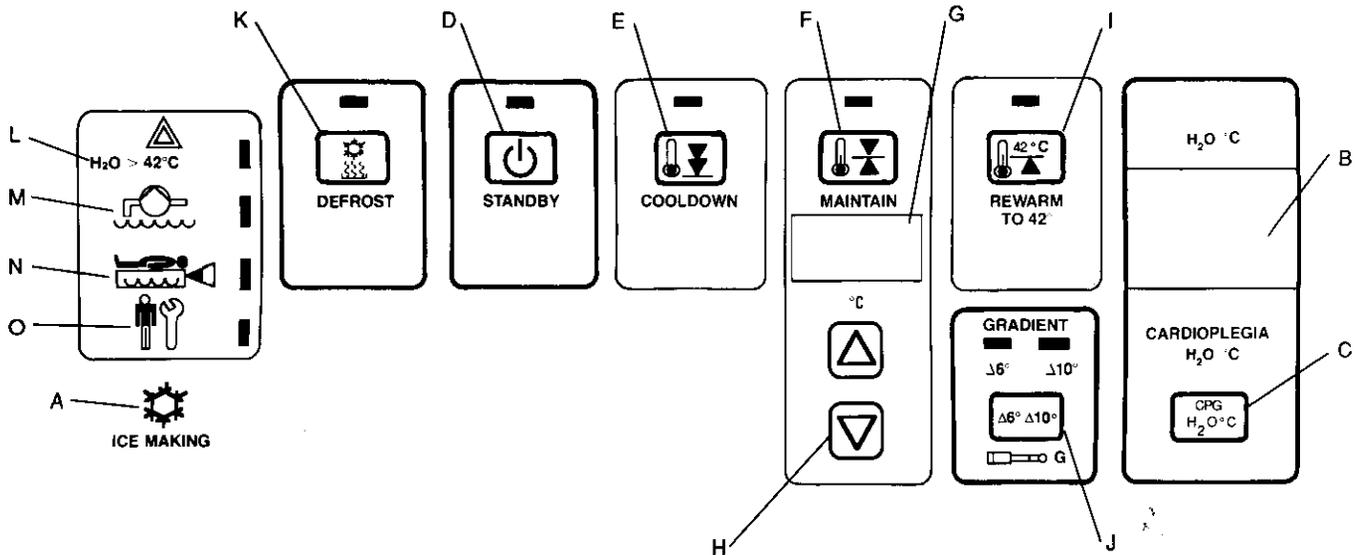


FIGURE 2: FRONT PANEL

- A. ICE MAKING Indicator Lamp lights when the ice making function is active.
- B. Water Temperature Display shows the output water temperature.
- C. Cardioplegia Water Switch allows momentary display of the cardioplegia outlet water temperature on the Water Temperature display.
- D. STANDBY (Mode) Switch selects a neutral mode in which temperatures may read but valves, pumps, and heaters are not operating (except during startup when the valves open to allow internal priming).
- E. COOLDOWN (Mode) Switch opens valves to circulate cold water from the large tank.
- F. MAINTAIN (Mode) Switch begins warming water or adding cold water to attain and maintain an operator-selected temperature.
- G. Maintain Temperature Display shows the selected maintain temperature. During startup, this display shows the software version and then 25°C.
- H. MAINTAIN TEMPERATURE Switches raise or lower the maintain temperature setting within a range of 0°-42°C.
- I. REWARM (Mode) Switch activates the heaters to warm water at a maximum rate up to 42°C and circulates the warm water.
- J. Gradient Switch limits the water temperature in Maintain or Rewarm modes to no more than 6°C or 10°C above the temperature read by Probe G. This switch is designed for use with a venous temperature probe. When the Gradient switch is inactive, the maximum rewarm temperature is automatically 42°C.
- K. DEFROST (Mode) Switch circulates warm water through the large tank until the water reaches 20°C; then the unit automatically reverts to Standby mode.
- L. H<sub>2</sub>O > 42°C LED lights to warn that the water temperature is at or above 42.5°C. The heaters are automatically turned off. The light and buzzer warnings will continue until the temperature is below 42°C.
- M. Pump Not Primed LED lights to warn that the main pump is not primed. The light and buzzer warnings will continue (or reoccur) until the pump is primed and restarted by pressing Cooldown, Maintain, Rewarm or Defrost.
- N. Low Flow to Blanket LED lights to warn that the water flow for the blanket is low.
- O. Service LED lights to warn that the temperature display and temperature control may be malfunctioning.

# Controls and Displays

## Cardioplegia Water Supply

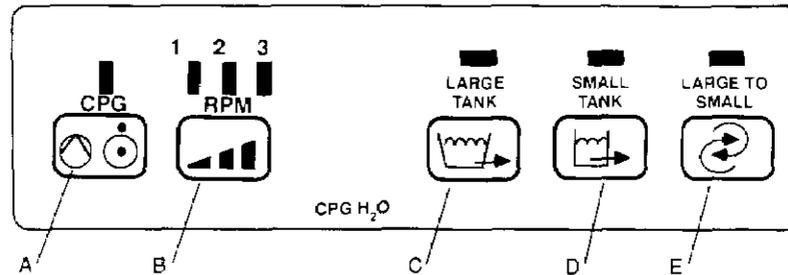


FIGURE 3: CARDIOPLEGIA PANEL

- A. Cardioplegia Switch (CPG) starts or stops the water circulating pump. Flow parameters are determined by the speed and water circuit selected.
- B. Speed Switch (RPM) selects the cardioplegia pump speed. LED 1 lights for low speed, LED 2 lights for medium speed, and LED 3 lights for high speed.
- C. LARGE TANK Switch sets the system to deliver water from the large tank to the cardioplegia water outlet.
- D. SMALL TANK Switch sets the system to deliver water from the small tank to the cardioplegia water outlet.
- E. LARGE TO SMALL Switch sets the system to recirculate water from the large tank to the small tank.

To display the water temperature, use the Cardioplegia Water switch on the main panel.

# Controls and Displays

## Temperature Display Module

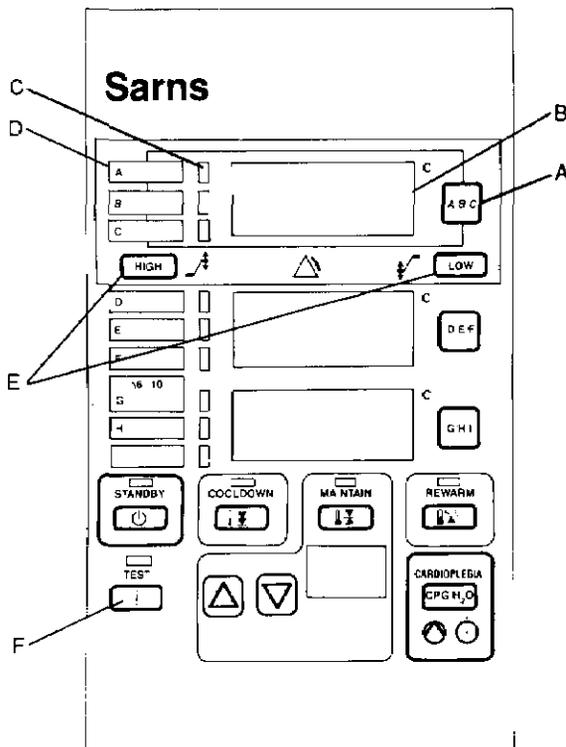


FIGURE 4: MODULE PANEL

At the top of this module are the controls and displays for temperature monitoring and at the bottom are remote controls and displays for the Sarns™ TCM II. The system will respond to the most recently entered information regardless of whether it is entered on the main panel or the remote panel.

- A. Probe Display Switch selects which probe's information will be displayed. Selections are marked on the switch. The probe LED lights to indicate the probe selected.
- B. Temperature Display shows the probe temperature and the following information:
  - Indicates that there is no probe connected or that the temperature is below  $-4^{\circ}\text{C}$ .
  - 99.9 Indicates that the temperature is over  $50^{\circ}\text{C}$ .
  - Blank indicates that there is no temperature conversion module or that the module is not functioning correctly.

The top display also displays the selection range and settings for the temperature limit alarms.

- C. Probe LED lights to identify which probe's information is being displayed. The LED's for probes A, B, or C also flash to indicate alarms. If the alarm limits for two probes are exceeded, both probe LEDs will flash; if one of these probes is also selected for display, its LED will flash at a higher rate.
- D. Probe Labels identify the probes. The labels are alphabetically marked to correspond with the probe outlets in the back of the main unit; erasable writing space is available to mark the probe location in the patient or extracorporeal circuit. Probe G is labeled "Gradient."
- E. HIGH and LOW Alarm Switches display or set temperature limit alarms for probes A, B, or C. When an alarm switch is depressed for less than one second, the alarm setting for the selected probe is displayed. When an alarm switch is depressed for more than one second, the display cycles through the selection range; releasing the alarm switch will set the last displayed number as the new alarm limit. If the temperature exceeds the alarm limit, a warning buzzer will sound once and the probe LED will flash.
- F. TEST Switch initiates a test to verify that the Temperature Probe Module is functioning correctly. During this test, the top display pertains to the first Temperature Probe Module, the middle display pertains to the middle Temperature Probe Module, and the bottom display pertains to the last Temperature Probe Module. When the test switch is depressed, the display must indicate  $25 \pm .4^{\circ}\text{C}$ ; the display will be blank if no module is connected. Releasing the test switch will return the display to its prior state.

The remote control switches function in the same manner as their counterparts on the main unit.

# Preparation

## Checking Ice and Water

1. See that the System Power is OFF.
2. Check that there is an adequate ice supply. A 50 lb. supply of ice should be sufficient for one case. To make additional ice, see "Using the Ice Maker" in the Operation section.
3. Add fresh cold water up to the maximum water level for each tank. The maximum water level for the large tank is indicated on the label located near the pressure switch in the large tank. The maximum water level for the small tank is attained when water begins overflowing from the small tank to the large tank.

## Connecting Equipment

Connect the Heat Exchangers and Blanket (Figure 5)

1. Use new sections of PVC tubing to connect equipment.
2. Prepare a drainage line for cardioplegia and arterial water Out lines: insert a ball-type valve (A) into the middle of a drainage line. Close the valve. Attach the drainage line to a tubing section with a tee (B).
3. Attach the water fittings (C) to the tubing sections and secure the connection with tubing clamps (D).
4. Attach the tubing sections to the heat exchangers and blanket.
5. Insert the water fittings into the appropriate In and Out ports on the system: CPG H<sub>2</sub>O for the cardioplegia heat exchanger, ART H<sub>2</sub>O for the arterial heat exchanger, and BKT H<sub>2</sub>O for a blanket.

Note: During use, keep the drain valves closed and do not drain attached equipment. The system ports are internally connected to a common water source such that draining the attached equipment may drain the entire system.

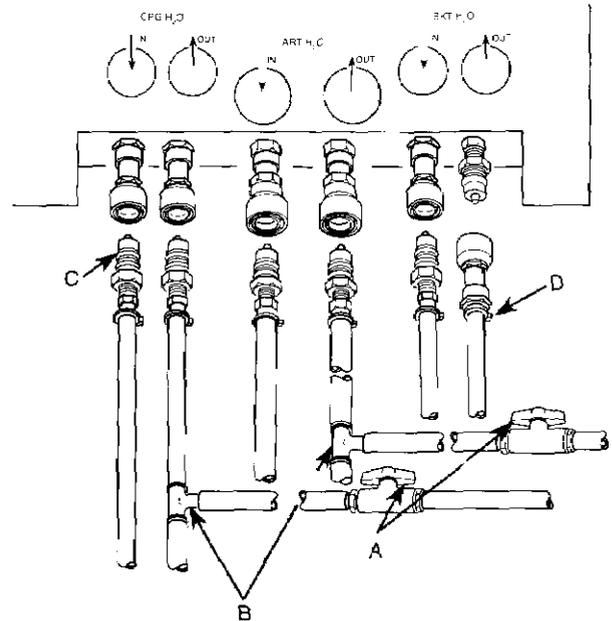


FIGURE 5: WATER CONNECTIONS

Connect the Display Module (Figure 6)

Select any 1 5/8 in. (4,1 cm) upright pole that is within 7.5 ft. (2,3 m) of the main unit. Lower the support bracket (A) over the pole until the bracket is at the desired position; tighten the thumbscrew (B). Position the back of the module so that its slot is directly over the desired support tab (C); pull the module downward until it is securely on the tab.

Connect the Temperature Display Module to the main unit before the System Power is turned on. Insert the module plug into the socket which is located in the pocket on the main unit. Be sure that this plug is securely connected.

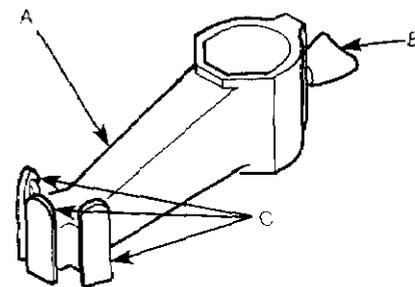


FIGURE 6: BRACKET

# Preparation

## Connect the Probes

**Warning:** To obtain accurate temperature readings, use only probes specified by Sarns for use with the Temperature Probe Module.

Insert the temperature probes into the sockets on the back of the system (see Figure 7). Each letter, A, D, G, etc., corresponds to a Probe Label on the remote unit.

Write the intended use of the probe on the corresponding Probe Label. Do not use permanent ink markers or coloring pens as they can stain the writing surface. Use a mild solvent or soft eraser to remove markings.

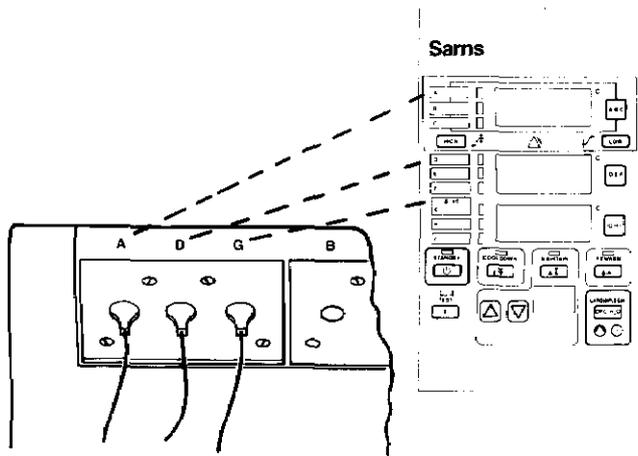


FIGURE 7: TEMPERATURE PROBE MODULES

Note: When rewarming to a gradient, Probe G must measure venous blood temperature.

## Starting and Priming the System

### Start the Unit

1. See that the Ice Maker and System Power switches are off.
2. Plug the power cord into a wall outlet of proper voltage, frequency, and capacity as indicated on the nameplate label.
3. Turn the System Power and Ice Maker on.

### Check the Startup Conditions

1. During the self test period, check that:
  - The buzzer sounds and the LEDs light for 3 seconds.
  - The buzzer stops and all the LEDs go off for 1 second.
  - The software version appears on the Maintain and Water Temperature displays for 3 seconds.
2. During the internal prime period, check that:
  - The Standby LED flashes, indicating that the system has automatically begun internal priming.
  - The Maintain Temperature display shows 25 °C on both the main and remote controls.
  - The high speed LED and the Large to Small Tank LED light on the cardioplegia water panel.
  - LEDs for Probes A, D, and G light and the temperature displays indicate the room temperature on the Temperature Display Module.
  - The Standby LED stops flashing once the internal prime is completed.
3. Before priming attached equipment, check that:
  - The water level is up to the maximum level.
  - The Standby LED lights continuously while the Cooldown LED flashes.

Note: Cooldown LED flashes once complete mode selection is available. Typically the operator will select Cooldown mode and start priming the attached equipment. However, if startup is the result of a system monitor circuit or a power failure the equipment will already be primed and it is possible to proceed to other modes.

If the startup conditions are incorrect, turn the System Power Switch off for 2 seconds, then back on, and check again. If they are still incorrect, do not use the equipment; contact Sarns Service, your local 3M subsidiary or your authorized Sarns distributor.

# Preparation

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## Starting and Priming the System (Continued)

### Prime the Attached Equipment

**Precaution:** The system must be properly primed; running the pumps and heaters with the device dry will damage them.

Remove air from the entire system including attached equipment:

1. Run in Cooldown mode until air bubbles disappear from the external tubing.
2. Turn the Cardioplegia on in Large Tank mode and run until all air bubbles disappear in the external tubing. Turn the Cardioplegia off.
3. Run in Rewarm mode to remove air from the internal warming circuit. If air bubbles appear in the external tubing, immediately change back to the Cooldown mode until the air bubbles disappear. Then alternate between Cooldown and Rewarm modes until the unit will operate in Rewarm mode without external air bubbles. Return to Standby mode.

Check the water level again.

**Precaution:** The water level in the large tank must never rise above the maximum level as water may damage the inside of the unit; this water level should not drop below the minimum level as there may be a loss of system performance (see maximum-minimum label).

## Test the Temperature Probe Modules

Depress the TEST switch; the displays must read  $25^{\circ} \pm .4^{\circ}\text{C}$ . If the readings fall outside this range, contact Sarns Service. Release the test switch and displays should show probe information if the probes are connected.

## Set the Alarm Limits

Select Probe A, B, or C; the probe LED will light. To set a high or low alarm limit, depress the appropriate alarm switch for over one second and the numbers appearing on the top display will cycle through the selection range. When the desired number appears, release the alarm switch to set the new alarm limit.

## Check the Remote Controls

Try the Maintain Up and Down switches. Change modes and check that modes function when using the remote unit and that the proper LEDs light on the remote and main panels.

If the unit does not respond properly to the above checks, do not use it; contact Sarns Service, your local 3M subsidiary or your authorized Sarns distributor.

## Using the System

**Warnings:** It is the operator's responsibility to use the Sarns™ TCM II and any attached equipment according to the manufacturer's instructions and good medical practices.

The Sarns™ TCM II is not completely automatic; responsibility for monitoring patient temperatures and rate of temperature change remains with the operator.

Do not depress the alarm switch for more than 1 second or the alarm setting will be changed.

Note: Following standard practices for electronic devices, monitor this equipment closely when it is exposed to intense electrical noise or fluctuating line voltage. Strong electromagnetic fields radiated from equipment elsewhere in the operating room (particularly defibrillators and electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.

### Mode selection

Use the **Standby** mode at any time to stop the pumps and heaters; this mode allows temperature monitoring without the selection of Cooldown, Maintain or Rewarm modes.

Use the **Cooldown** mode for maximum cooling.

Use the **Rewarm** mode for warming to a maximum of 42°C.

Use the **Maintain** mode to both cool or warm to a set water temperature and to maintain that water temperature:

- Maintain mode may be set and initiated after starting in either Cooldown or Rewarm mode; however, begin the Maintain mode before reaching the desired body temperature to prevent warming or cooling beyond the desired temperature.
- Maintain mode may be used to begin cooling or warming; beginning in the Maintain mode avoids the possibility of waiting too long to initiate the Maintain mode and thus overshooting the desired temperature.
- Maintain mode with several settings may be used for a sequence of water temperature changes to approximate rate control. In some cases it may be desirable to very slowly raise or lower the patient temperature. By setting several Maintain

temperatures, each a limited number of degrees warmer or cooler than the existing water temperature, the change in water temperature can be slowed down or varied considerably depending on the number of Maintain settings and the temperature difference between the settings. Maintain mode can not increase the rate of temperature change.

Use **Gradient Rewarming** to control the rate of rewarm. Select a gradient of 6° or 10° on the main panel. Check that Probe G is measuring the venous blood temperature. Use the Rewarm mode for a maximum water temperature of 42°C or set a Maintain temperature limit (on the main panel) and then use the Maintain mode.

NOTE: If there is an error condition for Probe G, the gradient selection will not function; instead, the unit will revert to Rewarm mode or Maintain mode without the gradient.

For cardioplegia, use the Large Tank or Small Tank for pressurized-water heat exchangers and the Large to Small Tank for drop-in heat exchangers.

### Additional Ice

A 50 lb. supply of ice should be sufficient for one case. Two hours between cases should be allotted for the compressor to partially replenish the ice supply; see "Using the Ice Maker".

To add ice to either tank during surgery, remove only an equivalent amount of water from the large tank by using the arterial water drainage line.

Note: During surgery, do not drain equipment attached to the system; as the ports are internally connected to a common water source, draining the attached equipment may drain the entire system.

Keep the tank covers in place during operation to help minimize temperature loss and keep debris out of the water. Do not stand or sit on the unit; weight may break the top.

**Precaution:** The water level in the large tank must never rise above the maximum level as water may damage the inside of the unit; this water level should not drop below the minimum level as there may be a loss of system performance (see maximum-minimum label).

# Operation

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## Resolving Alarm Conditions

When an alarm condition occurs, first try the suggested procedure. If the alarm condition continues, do not use the equipment; contact Sarns Service, your local 3M subsidiary or your authorized Sarns distributor. Whenever there is a major problem with the system, use an alternate source of water and means of temperature monitoring until the situation is corrected.

<u>Alarm Condition</u>	<u>Procedure</u>
H <sub>2</sub> O > 42°C Warning	<p>Switch to Cooldown mode until the water temperature reaches a satisfactory level; the warning LED will go out and the buzzer will stop when the temperature drops below 42°C. Return to Rewarm mode if desired.</p> <p><i>If this warning should activate with a minimal load, such as only a blanket attached, set the unit in Maintain mode at about 40 degrees until the additional equipment is attached.</i></p>
Pump Not Primed Warning	<p>If adequate water, try selecting any mode which will activate the main pump (Cooldown, Maintain, Rewarm or Defrost). If the alarm continues, check for leaks. Add water when necessary. Turn the power Off for two seconds and then back On. Use Cooldown, Cardioplegia and Rewarm to complete priming the system. Reset the controls and continue using the unit.</p>
Low Flow to Blanket Warning	<p>Check for leaks, kinks, or blockage in the tubing for the blanket.</p>
Service Warning	<p>If the Water Temperature display shows zero during this warning, do not use Maintain and Gradient Rewarm modes as temperature will increase to 42°C. Monitor the patient and water temperature closely to protect the patient and to assess the conditions of the unit; the surgical team must decide whether to continue using the Sarns™ TCM II or to change to an alternate source of water.</p>
Recurrence of Startup	<p>Check the startup conditions are correct. Reset controls; continue using the unit.</p>
Temperature Display Module panel blank due to problem with the module	<p>Unplug the remote from the main. Gradient rewarming may be continued although the venous blood temperature will not be displayed.</p>

## Correcting Equipment Problems

Slow or no water flow.

Check:

- Water supply. Priming requires water up to the fill line of the large tank.
- Outlet screens (in the bottom of tank) for blockage.
- Plumbing circuit for blockage.
- Plumbing for leaks; tubing for kinks or air.
- Water fitting connections.
- Attached equipment.

Slow or no cooldown.

Check the ice supply and the water flow.

Excessive noise.

Check the lines for air.

Compressor not running.

Check:

- Ice Supply. Sensor will turn the compressor off if the ice is already made; the Ice Making lamp will remain on.
- Operating mode. Compressor does not function in Defrost mode or whenever both heaters are on.
- Time that has elapsed since the switch was depressed. There is about a 4 minute delay after the switch is depressed before the compressor turns on.

Defrost mode will not start.

Check:

- Entry mode. Entry to Defrost mode must be from Standby mode.
- Ice supply or water temperature. If the water temperature is not below 20°C, the Defrost mode defaults to Standby mode.

6° or 10° gradient LEDs not functioning properly.

Check:

- Temperature Probe in the G socket for proper connection.

Temperature displays are incorrect.

Check:

- Probe Selection. See that the correct probe was chosen for display.
- Probes for proper connection.
- Probes for proper functioning; replace if necessary.
- Probe for proper placement.
- Probe labels for correct marking.
- Probe modules. Press test to check modules.

Startup does not occur on Temperature Display Module.

Check:

- Cord connection. See that it is properly connected to the main unit.

Remote screen goes blank.

Check:

- Cord connection. If the cord is disconnected from the socket, the Display Module may be reconnected: insert the plug in the socket; turn the System Power Off and then On in order to repeat startup for both the main and the display unit; reset all the modes, temperatures, and alarms on the main and remote panels.

Note that rewarming to a gradient may be continued without the Display Module in use but it will not be possible to display the temperature of Probe G.

Other Problems: First attempt to correct the situation by turning the System Power Off and back On. If the problem continues, contact Sarns Service, your local 3M subsidiary or your authorized Sarns distributor.

# Operation

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## Using the Ice Maker

Up to Ten hours before use:

1. Remove any attached equipment. Turn the System Power and Ice Maker On.
2. Use the Defrost mode to melt the ice off of the cold plate and sensor; excess ice or uneven or high ice buildup around the ice sensor may cause poor cooling performance, premature compressor shutoff or damage the pump.

Note: The Defrost mode can only be entered through the Standby mode.

When the water temperature reaches 20°C, the unit will automatically go into Standby mode. After about a 4 minute delay, the compressor will turn on.

3. Turn the System Power off once the compressor has started. Leave the Ice Maker On; the ice sensor will automatically turn the compressor off when an adequate amount of ice is made.

4. Check the ice block. A large block of ice should be formed around the cold plate. Ice should surround the ice sensor. There should be 1 to 1-1/2 in. (2,5 to 3,8 cm) of water between the front and rear of the tank and the ice block. The sides of the ice block may touch the tank.

Ice may be saved for 48 hours. After 48 hours, follow the Cleaning and Disinfecting Procedure in the Maintenance Section. The unit may be stored indefinitely only when cleaned and drained.

To replenish ice between surgical procedures:

Note: Defrost is not necessary when an operator is monitoring the ice maker.

1. Turn the Ice Maker On and select Standby mode.
2. Fill the large tank to the maximum level with fresh cold water and replace the cover. The Ice Making LED will light to indicate ice is being made.
3. Check to see the sensor has turned the compressor off when an adequate supply of ice is made.

# Maintenance

## Cleaning Procedure

Clean the Sarns™ TCM II every 2-3 days. The water tanks must be disinfected to prevent a high bacteria count and then thoroughly rinsed and drained to remove residual chemicals.

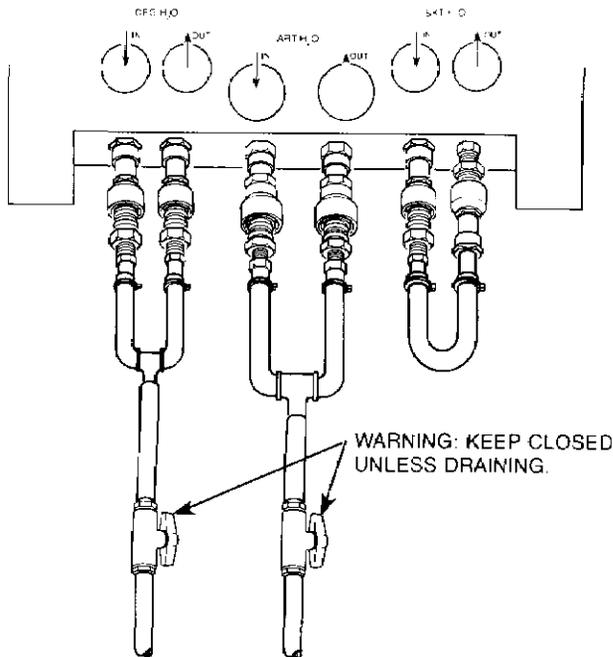


FIGURE 8: CLOSED CIRCUITS

1. **Make closed circuits** by connecting each set of In and Out ports with about 2 ft. (0,6 m) of tubing (see Figure 8); include a ball-type valve and drainage line in the cardioplegia and arterial water circuits. Position the unit near a sink or floor drain.
2. **Add water and prime the pump.** Fill both tanks to the maximum level. Turn the System Power On. Run for 1 minute in Cooldown mode to remove air.
3. **Defrost if ice is present.** Turn the Ice Maker Off so that the unit will not automatically remake ice after defrosting. Run the unit in the Defrost mode until the ice bank is melted (approximately 2 hours, depending on amount of ice).  
**Note:** The Defrost mode can only be entered through the Standby mode.
4. **Drain both tanks completely** to remove the contaminated water. Turn the System Power Off and back On again to open the internal valves; open both drain valves to empty the tanks. Close the drain valves.
5. **Add fresh tap water and prime,** as in step 2 above.

6. **Lower the water level** in the large tank until only 6 in. (15,2 cm) of water remains in the bottom. Lower the water by gravity draining or by pumping:
  - Select Standby mode and gravity drain into a floor drain or bucket, OR
  - Select Cooldown mode and pump the water through the drain hose into a sink or floor drain.

**Note:** If prime is lost, refill the large tank, reprime the system and lower the water level again. Leave the small tank full during cleaning.
7. **Add the disinfectant to the large tank only.**

**Precaution:** Use only glutaraldehyde based disinfectants such as Cidex™, Glutarex™, or Sporicidin™\*, as other cleaning agents may cause corrosion.

Add the disinfectant concentrate according to the manufacturer's recommendations for the amount of water in the system. Do not mix the disinfectant any stronger than the recommended strength; a more concentrated solution may damage the plumbing of the device. When calculating dilution of disinfectant, be aware that there are about 5 gallons (19 liters) of water in the system if the large tank is drained down to 6 in. (15,2 cm) of water, the small tank is filled, and the system is primed.

8. **Operate the unit in each mode.** Turn the cardioplegia On at medium speed and operate in each mode for 10 minutes as directed below. Scrub the tanks with a bottle washer or similar brush, being careful of the ice sensor and bracket. Be sure the outlet screens on the bottom of the tanks are clean and clear of debris. Screens may be removed temporarily for cleaning. Screens should be replaced periodically. Do not operate the unit without screens.

Mode Selections with CPG On at #2 RPM	Time per Mode
Cooldown with Large to Small	10 minutes
Defrost** with Small Tank	10 minutes
Rewarm with Large Tank	10 minutes

\* Cidex is a trademark of Johnson & Johnson, New Brunswick, NJ, USA; Glutarex is a trademark of 3M, St. Paul, MN, USA; Sporicidin is a trademark of Sporicidin International, Rockville, MD, USA

\*\*The Defrost mode will default to Standby mode when the water temperature reaches 20°C. In this case, Standby mode may be used to complete cleaning of the small tank.

# Maintenance

## Cleaning Procedure (Continued)

9. Drain both tanks of cleaning solution, as in step 4 above.
10. Flush the system with fresh tap water. Close both drain valves. Add water and prime the pump, repeating step 2. Drain completely as in step 4. Repeat flushing until all disinfectant is removed. Remove the external tubing.
11. Clean the system. Wipe the cabinet with a damp cloth. Keep water out of the displays, away from the probe jacks, and away from all switches. Clean the writing spaces with a soft eraser; do not use any abrasive material.
12. Clean the refrigeration coils every 3 months.

**Precaution:** Remove any lint from the refrigeration coils to prevent damaging the ice maker. Take care when cleaning the refrigeration coils as the coils have sharp edges.

Disconnect the unit from its wall power supply. Remove the rear panel and the left rear panel (corner away from the small tank) Use a soft brush and vacuum to remove lint from the coils. Replace the panels. Plug the unit back into the appropriate wall power supply.

13. Make new ice or store the unit.

To make new ice: fill the large tank to the maximum level with fresh cold water and replace the cover; turn the Ice Maker On. The Ice Making LED will light to indicate ice is being made, but all other LEDs will be off.

To store the unit: turn the System Power Off; wipe the unit and tanks dry; replace the tank covers and store. Always dry the system before storing it.

## Periodic Operator Checks

The following tests may be performed periodically between the 6 month service checks made by Sarns Service.

### Temperature Accuracy

1. Connect the ART In and Out ports with tubing to make a closed circuit.
2. Attach a Temperature Probe and a temperature measuring device to the closed circuit.
3. Set various temperatures; once each temperature is attained, compare the readings for the Maintain setting, the water temperature display, and the measuring device. All temperatures should be within 1°C of each other.

## Operating Modes

1. Set a Maintain temperature of 30°C and begin Maintain mode; the water temperature display should stabilize at 30°C.
2. Change to Rewarm mode; the water temperature should rise.
3. Change to Cooldown mode; the water temperature should drop.

## H<sub>2</sub>O > 42°C Warning

1. Operate the unit in Rewarm mode until up to 42°C; check with a measuring device that the water outlet temperature remains below 42°C.
2. Add sufficiently hot water to the large tank to exceed 43°C; check that the H<sub>2</sub>O > 42°C Warning LED lights and the alarm sounds.

## Low Flow to Blanket Warning

If using the Blanket Supply, select Cooldown, Maintain, or Rewarm mode and kink the tubing leading to the blanket In port; within 20 seconds, the Low Flow to Blanket LED should light. Unkink the tubing and the LED should go out.

## Current Leakage

Maximum current leakage should not exceed 100 microamps when the unit is in any mode. To measure the current leakage, refer to Underwriters Laboratory or IEC Standards for the correct procedure.

## Alarm Limit Accuracy

1. Set a low alarm for 12°C. Test Probes A, B, and C by placing the probe in ice cold water; the warning alarm should sound and the probe LED flash. Remove the probe from the water and the alarm should stop.
2. Set a high alarm for 30°C. Test Probes A, B, and C by placing the probe in water which is over 30°C; the warning alarm should sound and the probe LED flash. Remove the probe from the water and the alarm should stop.

## Sarns Service Checks

It is recommended that the entire system have a maintenance inspection every six months to ensure proper operation. Maintenance inspections and repairs are to be conducted only by Sarns Service or your authorized Sarns distributor.

# Maintenance

## Accessories

The following accessories are available for use in setting up the Sarns™ TCM II and attached equipment for operation and for use in cleaning the unit.

	<u>Size</u>	<u>Quantity</u>	<u>Part No.</u>	<u>3M I.D. No.</u>
ARTERIAL HEAT EXCHANGER SUPPLY 16040010 (3M I.D. No. 78-8066-7416-0)				
Water Fitting	1/2 in. (12,7 mm)	2	16052010	78-8066-7421-0
Barbed Connector	1/2 in. (12,7 mm)	2	25324011	26-1008-4365-0
Hose Clamps		9	25325020	26-1008-4380-9
Drainage Line Assembly				
Tubing	1/2 in. (12,7 mm) ID x 10 ft. (3,04 m)	1	30108113	26-1008-4429-4
Nylon Tee	1/2 in. (12,7 mm)	1	25612022	26-1008-4367-6
Ball Valve	1/2 in. (12,7 mm)	1	14191010	78-8066-7165-3

### BLANKET SUPPLY 16042010 (3M I.D. No. 78-8066-7418-6)

Water Fitting for Out	1/4 in. (6,4 mm)	1	16053010	78-8066-7422-8
Water Fitting for In	1/4 in. (6,4 mm)	1	16131010	78-8066-7437-6
Barbed Connector	1/4 in. (6,4 mm)	2	25321029	26-1008-1827-2
Hose Clamps		5	25325020	26-1008-4380-9

### CARDIOPLEGIA WATER SUPPLY 16041010 (3M I.D. No. 78-8066-7417-8)

Water Fitting	3/8 in. (9,5 mm)	2	16051010	78-8066-7420-2
Barbed Connector	3/8 in. (9,5 mm)	2	25324010	26-1008-1828-0
Hose Clamps		9	25325020	26-1008-4380-9
Drainage Line Assembly				
Tubing	3/8 in. (9,5 mm) ID x 10 ft. (3,04 m)	1	30106093	26-1008-4427-8
Nylon Tee	3/8 in. (9,5 mm)	1	25612021	26-1008-0549-3
Ball Valve	3/8 in. (9,5 mm)	1	16048010	78-8066-7419-4

### TEMPERATURE DISPLAY MODULE 15746 (3M I.D. No. 98-0702-0137-5)

### TEMPERATURE PROBE MODULE 15745 (3M I.D. No. 98-0702-0136-7)

These modules include directions for installation or replacement by a Certified Clinical Engineer, Biomedical Engineer, Biomedical Electrical Technician, or those trained to service Sarns equipment.

### TEMPERATURE PROBES

Any YSI (Yellow Springs Instrument) 400 Series Probe or Sarns equivalent probe.



# Product Description

## Specifications

### Electrical

Power Supply	Catalog Numbers	
	4415	4416
Voltage	108 - 122 V ~ (115 V nominal)	210 - 250 V ~ (220-240 V nominal)
Frequency	60 Hz	50 Hz
Amperage*	16 A	12 A
Current Leakage	100 microamps maximum for 115 V. 500 microamps maximum for 220 V.	
Ground Resistance	.1 Ohm maximum	

\*Note: Sarns™ TCM II amperage specifications are applicable to normal clinical operating conditions. Normal clinical operating conditions do not include making ice in Maintain mode when the water in the large tank is  $\geq 20^{\circ}\text{C}$ .

### Dimensions

	<u>Main Unit</u>	
Height:	34.5 in. (87,6 cm)	
Width:	20 in. (50,8 cm)	
Depth:	29.5 in. (74,9 cm)	
Weight:	294 lbs. (133,4 kg) with the tanks empty 386 lbs. (175,1 kg) with the tanks full	
	<u>Large Tank</u>	<u>Small Tank</u>
Length:	18.5 in. (47,0 cm)	9.5 in. (24,1 cm)
Width:	8.7 in. (22,1 cm)	5.5 in. (14,0 cm)
Depth:	21.5 in. (54,6 cm)	9.3 in. (23,6 cm)
Capacity: Water or Crushed Ice	9 gal. (34 L) 40 lbs. (18,1 kg)	1.2 gal. (4,5 L) 7.5 lbs. (3,4 kg)
	<u>Temperature Display Unit</u>	<u>Temperature Probe Modules</u>
Height:	8-3/4 in. (22,2 cm)	9 in. (22,9 cm)
Width:	5-1/2 in. (14,0 cm)	5-3/4 in. (14,6 cm)
Depth:	2-1/2 in. (6,4 cm)	2-1/2 in. (6,4 cm)

# Product Description

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## Specifications (Continued)

### Performance

#### Water Outlet Temperature

Arterial Heat Exchanger and Blanket: 0-42°C.  
Cardioplegia: ice water only.

#### Maximum Flow Performance (1/8 hp Pump)

Arterial Heat Exchanger\* outlet port:  
5.5 gal/min (21.0 L/Min) at zero head  
13.5 psi (700 mmHg) maximum pressure

Blanket Supply\* outlet port:  
.8 gal/min (3.0 L/Min) at zero head  
11.8 psi (610 mmHg) maximum pressure

Cardioplegia Water Supply port:  
2.1 gal/min (7.8 L/Min)  
7.5 psi (386 mmHg) maximum pressure

### Ice Supply

If the large tank is filled to the maximum level with 25°C water, the Ice Maker can provide a maximum of 50 lbs (22,7 kg) in 8 hours.

If the large tank is filled to the maximum level with 3°C water, the Ice Maker can provide a minimum of 33.5 lbs (15,1 kg) in 3 hours.

Temperature Probe Module operating range: 0-50°C  
Remote temperature sensing and display accuracy:  $\pm 0.3^\circ\text{C}$

### Venous differential mode:

6° gradient = rewarm water temperature is held to a maximum of 6°C more than the incoming venous blood temperature.

10° gradient = rewarm water temperature is held to a maximum of 10°C more than the incoming venous blood temperature.

\*Note: Performance will be different with both a heat exchanger and a blanket being supplied water at the same time.

# Product Description

## Functional Description

### Main Unit

The main unit, which supplies water for both blood heat exchangers and blankets, has five modes of operation. The Standby mode allows temperature readouts without the pump or heaters running. In Cooldown mode (see Figure 9) the pump draws through the ice water tank for maximum cooling. In Rewarm mode (see Figure 10) the pump draws water past the heaters for maximum warming to 42°C. In Maintain mode (see Figures 11, 12 and 13) the operator selects a water temperature; water is drawn either past the heaters or from the ice water tank to attain and maintain the selected temperature.

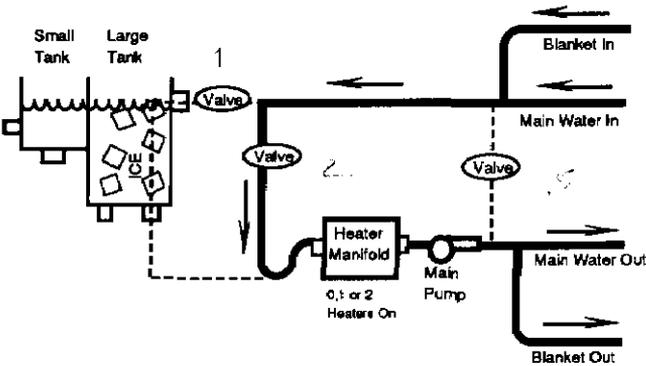


FIGURE 11: MAINTAIN MODE  
(Set Temperature Greater Than or Equal to Water Temperature)

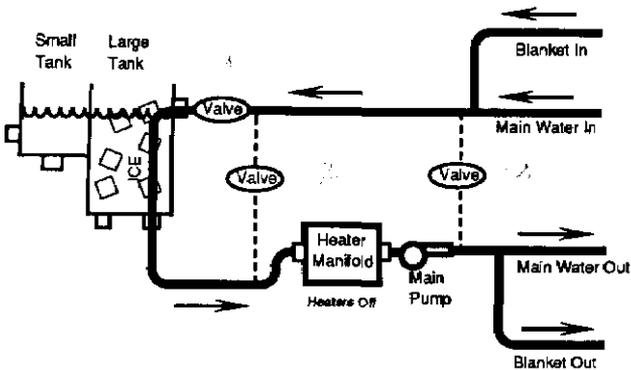


FIGURE 9: COOLDOWN MODE

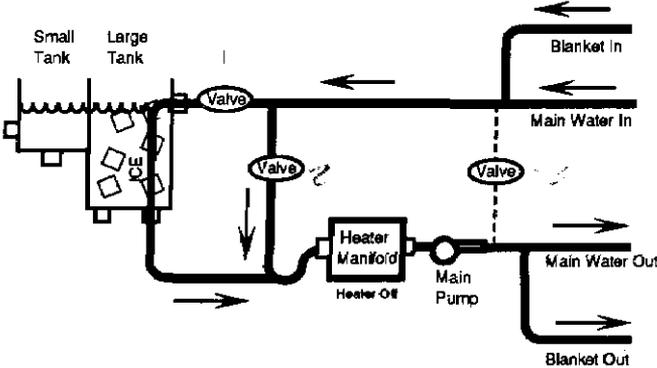


FIGURE 12: MAINTAIN MODE  
(Set Temperature Slightly Less Than Water Temperature)

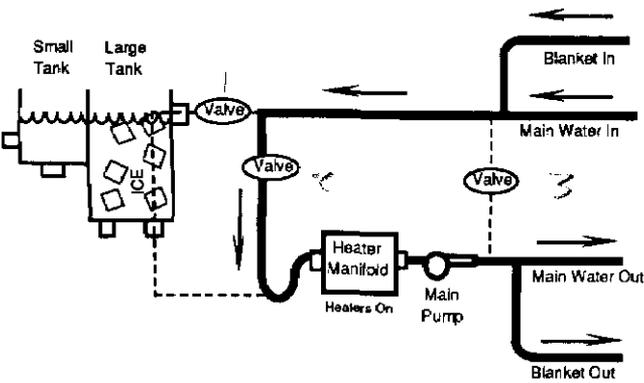


FIGURE 10: REWARM MODE

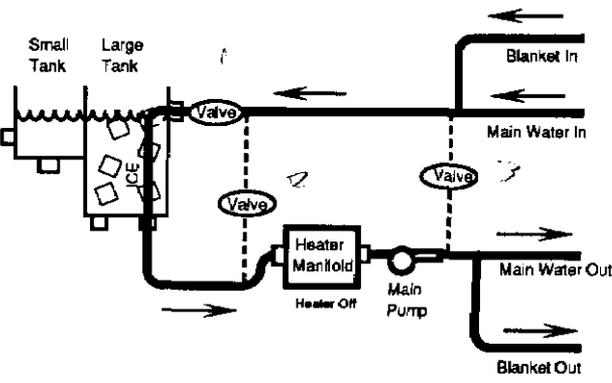


FIGURE 13: MAINTAIN MODE  
(Set Temperature Much Less Than Water Temperature)

# Product Description

## Functional Description (Continued)

In Defrost mode (see Figure 14) the pump draws water past the heater and recirculates it through the large tank. To prevent accidentally defrosting the unit, Defrost mode must be entered from Standby mode. In all five modes the outlet water temperature appears on the digital display.

The Sarns™ TCM II includes various safety features. During startup, the unit automatically runs a self test on the system's internal functions and opens the valves to prime the pump. It alerts the operator by sounding an alarm and lighting warning indicators if it detects overtemperature of the water, an unprimed pump, low flow for the blanket or an internal temperature sensor failure. A system monitor circuit checks for computer problems; if a problem is detected, the pump heaters are stopped and the unit attempts to repeat startup.

The Ice Maker can build at least 19 lbs. (8.6 kg) supply of ice in 3 hours or it can produce an entirely new supply of 50 lbs. (22.7 kg) in 8 hours. The Defrost mode will turn off the compressor, defrost until the water temperature reaches 20°C, and reactivate the compressor to build an ice supply which is evenly distributed around the cold plate.

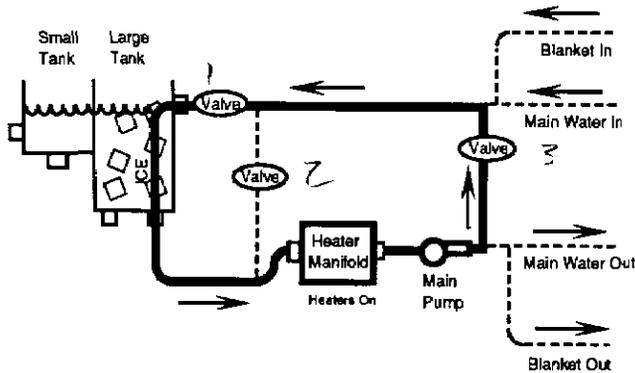


FIGURE 14: DEFROST MODE

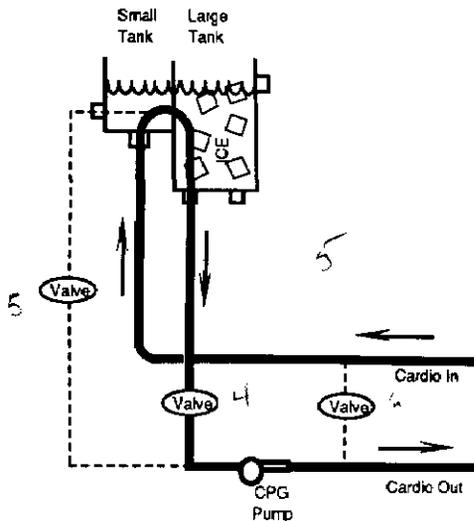


FIGURE 15: LARGE TANK CPG

## Cardioplegia Water Supply

The system will provide water to cool clear or blood cardioplegia. Three pump speeds allow variation of the cooling rate of the cardioplegia by changing the water flow rate. Three water supply modes are available to accommodate different heat exchangers and demands. A Large Tank mode (see Figure 15) pumps water from the large tank to external outlets for use with pressurized-water heat exchangers. A Small Tank mode (see Figure 16) pumps water from the small tank to external outlets for use with pressurized-water heat exchangers; this allows independent cardioplegia cooling. A Large to Small Tank mode (see Figure 17) recirculates water from the large to the small tank and back for use with drop-in heat exchangers.

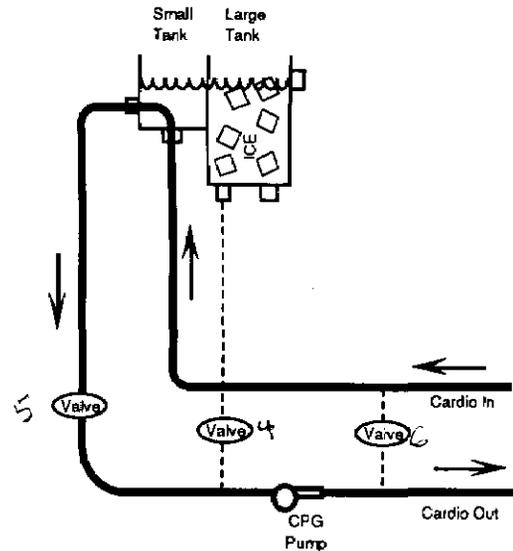


FIGURE 16: SMALL TANK CPG

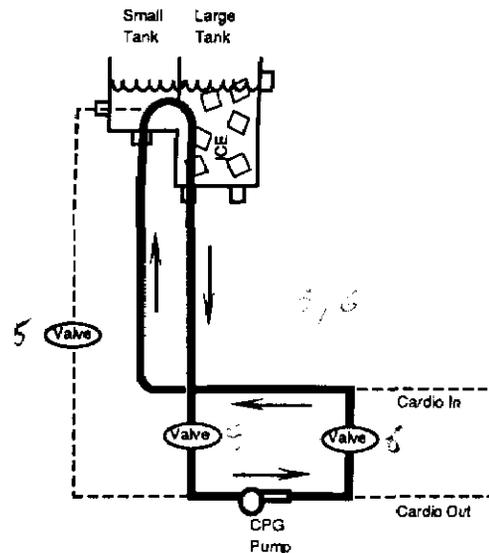


FIGURE 17: LARGE TO SMALL CPG

# Product Description

## Functional Description (Continued)

### Temperature Display Module

The Temperature Display Module may be used to monitor the temperature of the patient or extracorporeal circuit. Temperature probes are connected to a Temperature Probe Module, which is installed in the rear of the system. One Temperature Probe Module will translate information from three probes for display on the three digital displays. Up to nine temperature readings are available with the use of three Temperature Probe Modules and nine temperature probes. Probe Display switches are used to select which probe's information will be displayed. LEDs, next to alphabetically marked labels, indicate which probe has been selected. These labels have an erasable writing surface for marking the probe location in the patient or extracorporeal circuit. High and low temperature alarm limits may be set for one probe per module.

Gradient rewarming frees the operator from constant monitoring and setting of temperatures. When Probe G is measuring the venous blood temperature, gradient rewarming may be used to limit the warming rate of water to 6° or 10° above the temperature of the venous blood. Selecting a gradient while in Rewarm mode limits the maximum water temperature to 42°C; selecting a gradient while in Maintain mode allows the operator to select a maximum water temperature lower than 42 °C.

The Temperature Display Module's remote control function duplicates the main unit cooling, warming, and maintain controls and the cardioplegia pump On/Off switch. The module may be mounted on a vertical pole up to 7.5 ft. (2,3 m) from the main unit; the remote controls allow convenient operation of the main unit while monitoring temperatures.

For safety, the Test switch may be used to check the temperature conversion circuitry and displays. A remote monitor circuit automatically checks for internal problems; it will cause all the panel lights to go off if a problem is detected.

### Theory of Operation

For an arterial heat exchanger or blanket supply, water is drawn by the pump 1) from a cold water reservoir for maximum cooling, 2) in a closed path past electric heaters for maximum warming, or 3) in a path with either cold reservoir water added or heat added to attain and maintain a set temperature. Microprocessors translate and compare thermistor probe measurements to the selected temperature;

then they operate the correct valves and electric heaters to adjust the water temperature. The microprocessors also translate the probe measurements for digital display.

When a gradient relative to the venous blood temperature is used for rewarming, microprocessors measure the difference between venous blood temperature and water temperature and control the valves and heaters to maintain the correct differential.

The Sarns™ TCM II is designed to provide protection against excessively high temperatures. The maximum temperature available for operator selection is limited to 42 °C. The software compares the primary and redundant temperature probes in the heaters to verify temperature accuracy; the software will give an alarm and shut off the heaters if the temperature reaches 42.5 °C. In the event of software failure, a completely separate monitoring system with an emergency circuit will shut off the heaters at 43.0 °C.

The ice maker is a compressor type refrigeration system which uses Dichlorodifluoromethane (R-12) for the refrigerant gas. The water freezes onto a cold plate located in the large tank. A sensor, near the cold plate, turns off the compressor when approximately 50 lbs. of ice has collected. The microprocessor disables the compressor when in the Defrost mode.

For Cardioplegia Water Supply, water is 1) drawn by a pump from a water reservoir, supplied to an external port, and returned; or 2) drawn from the large water reservoir, supplied to a small water reservoir, and returned to the large reservoir. The pump operates at three speeds to change the water flow rate. The mode and speed selections are activated by the cardioplegia switch.

For patient temperature monitoring, a thermistor, at the tip of each telethermometer probe, senses external temperature. When there is a shift in the external temperature, the electrical resistance of the thermistor changes accordingly. This resistance change is measured by the Temperature Probe Modules, and transmitted for display.

The remote controls function in the same manner as their counterparts on the main unit. Choosing a mode on the remote panel causes the appropriate information to be sent to the main unit. The main unit acknowledges receiving the information by returning the information to the remote unit and lighting the correct remote LED. The display of the LEDs on the remote unit indicates the change has been received on the main panel.